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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Barbara Enenkel et al ) Art Unit: 1632  
U.S. Appln. No. : 10/724,266 ) Examiner: To be assigned  
Confirmation No. : 1242  
U.S. Filing Date : November 26, 2003  
Title of Invention : EXPRESSION VECTOR, METHODS FOR THE PRODUCTION OF  
HETEROLOGOUS GENE PRODUCTS AND FOR THE SELECTION  
OF RECOMBINANT CELLS PRODUCING HIGH LEVELS OF SUCH  
PRODUCTS  
Attny. Docket No. : 1/1412

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

June 21, 2004

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

*Susan K. Pocchiari*

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Attorney for Applicant(s)  
Reg. No. 45,016

Patent Department  
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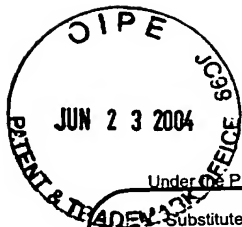
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on June 21, 2004.

*Susan K. Pocchiari*

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PTO/SB/08a (08-03)

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Substitute for form 1449A/PTO		Complete if Known	
		Application Number	10/724,266
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Filing Date	November 26, 2003
		First Named Inventor	Barbara Enenkel et al
		Art Unit	1632
		Examiner Name	To be assigned
		Attorney Docket Number	1/1412

Sheet 1 of 5

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 6,063,598	05/16/2000	Barbara Enenkel et al	
		US- 4,656,134	04/07/1987	Gordon M. Ringold	
		US- 5,179,017	01/12/1993	Richard Axel et al	
		US- 5,491,084	02/13/1996	Martin Chalfie et al	
		US- 6,146,826	11/14/2000	Martin Chalfie et al	
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FOREIGN PATENT DOCUMENTS						
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 97/15664	05/01/1997	Dr. Karl Thomae GmbH		
		WO 98/32869	07/30/1998	Neurosearch		
		WO 02/094325 A2	11/28/2002	Boehringer Ingelheim International GmbH		
		WO 01/04306 A1	01/18/2001	Genentech, Inc.		
		WO 99/53046	10/21/1999	Chiron Corporation		

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		DE 19539493 A1	04/30/1997	Dr. Karl Thomae GmbH		

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Application Number	10/724,266
Filing Date	November 26, 2003
First Named Inventor	Barbara Enenkel et al
Art Unit	1632
Examiner Name	To be assigned
Attorney Docket Number	1/1412

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		CHARLES G. BAILEY ET AL; High-Throughput Clonal Selection of Recombinant CHO Cells Using a Dominant Selectable and Amplifiable Metallothionein-GFP Fusion Protein; Biotechnology and Biomolecular 12/20/2002 Vol. 7 page 670-676; Wiley Periodicals, Inc.	
		XUEDONG LIU ET AL; Generation of Mammalian Cells Stably Expressing Multiple Genes at Predetermined Levels; Analytical Biochemistry (2000) Vol. 9 pages 20-28; Academic Press	
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		GAIL URLAUB ET AL; Deletion of the Diploid Dihydrofolate Reductase Locus from Cultured Mammalian Cells; Cell (June 1983) Vol. 33 pages 405-412; Department of Biological Sciences, Columbia University, New York, NY	
		YOSHIKAZU SUGIMOTO ET AL; Efficient Expression of Drug-selectable Genes in Retroviral Vectors Under Control of an Internal Ribosome Entry Site; Biotechnology (July 1994) Vol. 12 pages 694-698; National Cancer Institute	
		N. RAMESH ET AL; High-titer bicistronic retroviral vectors employing foot-and-mouth disease virus internal ribosome entry site; Nucleic Acids Research (1996) Vol. 24 No. 14 pages 2697-2700; Oxford University Press	

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		MICHAEL PRIMIG 1 ET AL; A novel GFPneo vector designed for the isolation and analysis of enhancer elements in transfected mammalian cells; International Journal of Genes and Genomes (1998) Vol 215 pages 181-189; Elsevier Science B.V.	
		JERRY PELLETIER ET AL; Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA; Nature (July 1988) Vol. 334 pages 320-325; Department of Biochemistry McGill Cancer Center, McGill University Montreal Canada	
		RICHARD A. MORGAN ET AL; Retroviral vectors containing putative internal ribosome entry sites: development of a polycistronic gene transfer system and applications to human gene therapy; Nucleic Acids Research (February 10, 1992) Vol. 20 No. 6 pages 1293-1299; Molecular Hematology Branch, Bethesda MD.	
		LUCIA MONACO ET AL; Expression of recombinant human granulocyte colony-stimulating factor in CHO dhfr -cells: new insights into the in vitro amplification expression system; Gene (1996) Vol. 180 pages 145-150; Elsevier Science B.V.	
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		SUNG K. JANG ET AL; Initiation of Protein Synthesis by Internal Entry of Ribosomes into the 5' Nontranslated Region of Encephalomyocarditis Virus RNA In Vitro; Journal of Virology (April 1989) Vol. 63 No. 4 Pages 1651-1660; American Society for Microbiology	
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		MARTIN CHALFIE ET AL; Green Fluorescent Protein as a Marker for Gene Expression; Science (February 11, 1994) Vol. 263 pages 802-805; Department of Biological Sciences, Columbia University New York, NY	

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First Named Inventor

Barbara Enenkel

Art Unit

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		MONIQUE V. DAVIES ET AL; The Sequence Context of the Initiation Codon in the Encephalomyocarditis Virus Leader Modulates Efficiency of Internal Translation Initiation; Journal of Virology (April 1992) Vol. 66 No. 4 pages 1924-1932; American Society for Microbiology	
		MOHAMMED A. ADAM ET AL; Internal Initiation of Translation in Retroviral Vectors Carrying Picornavirus 5' Nontranslated Regions; Journal of Virology (September 1991) Vol. 65 No. 9 pages 4985-4990; American Society for Microbiology	
		RANDAL J. KAUFMAN ET AL; Amplification and Expression of Sequences Cotransfected with a Modular Dihydrofolate Reductase Complementary DNA Gene; J. Mol. Biol. (1982) Vol. 159 pages 601-621; Center for Cancer Research and Department of Biology, Cambridge Mass.	
		International Search Report Reference No. PCT/EP 03/13225	

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